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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|----------------------|-------------------------|---------------------------|
| 09/851,400 | 05/07/2001 | Michael L. Reo | 020 | 1900 |
| 7. | 590 12/15/2004 | | EXAM | INER |
| HOEKENDIJK & LYNCH, LLP | | | DESANTO, MATTHEW F | |
| P.O. Box 4787 Burlingame, CA 94011-4878 | | ART UNIT | PAPER NUMBER | |
| | | | 3763 | |
| | | | DATE MAILED: 12/15/2004 | . DATE MAILED: 12/15/2004 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|--|---|--|-----------------------|--|--|--|
| Office Action Summary | | | | | | |
| | | 09/851,400 | REO ET AL. | | | |
| | | Examiner Methew F DeSente | Art Unit | | | |
| | The MAILING DATE of this communication app | Matthew F DeSanto | orrespondence address | | | |
| Period fo | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on <u>16 N</u> | ovember 2004. | | | | |
| 2a)⊠ | This action is FINAL . 2b) This action is non-final. | | | | | |
| 3)□ | • | | | | | |
| Disposit | ion of Claims | | | | | |
| 4) Claim(s) 1,3-23 and 25-48 is/are pending in the application. 4a) Of the above claim(s) 3-6,33-40,42,47 and 48 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1, 7-23, 25-32, 41, 43, 46 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicat | ion Papers | • | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) | 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachmen | t(s) | | | | | |
| 1) Notice 2) Notice 3) Inform | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed May 19, 2003 and August 8, 2003 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 2. Claims 1, 7-19 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially smooth" in claim 1 is a relative term, which renders the claim indefinite. The term "substantially smooth" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term does not adequately independently describe the exterior surface of the anastomotic component and therefore should be amended, without the addition of new matter, in order to be given patentable weight.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 4. Claims 1,7,8, 10-23,25,27-32,41,43-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Cole.
- 5. Cole teaches a device for forming anastomosis in patients using magnets generally comprising two main securing components that are coated with biocompatible materials. One of the materials used for the securing components is NdFeB, and the coating layer can be, for example, a 0.001 inch thick layer of a magnetic material (column 7, line 45) or a layer of Gold (column 8, line 22). The securing component may have elements to enhance its engagement to the vessel wall (column 11, lines 63-67). Applicant does affix the same materials to the component as disclosed by Cole, and while not expressly mentioned in the Cole patent, processing the surface of the component in preparation for the receipt of biocompatible materials is standard industry practice.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9, 12, 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole as applied to the claims above, and further in view of Whayne.

Cole, as described above teaches a magnetic anastomosis device, but fails to teach the surface of the device being electropolished.

Whayne teaches an anastomosis device coated with a biocompatible material such as gold (0067). The surface of the device may be electropolished and then plated with the biocompatible material (0067).

It would have been obvious to one skilled in the art at the time of the invention to electropolish the surface of the anastomotic component in order to reduce platelet adhesion to the surface.

Response to Arguments

- 8. Applicant's arguments filed 11/16/04 have been fully considered but they are not persuasive.
- 9. The applicant fails to address the prior art, and therefore the rejections stand and this action is made final.

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Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto Art Unit 3763

December 1, 2004

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